IRB Committee Member – Adverse Event (AE) Single Member Review

When an Adverse Event (AE) is reported by the study team, IRB Staff will assign it to the appropriate reviewer(s). Once an AE is assigned to you for review, it can be found under My Reviews in the Inbox of your Home Workspace.

eResearch Home Workspace

1. Click the Committee Member role or verify that it is selected on the Home Workspace.
2. Click the Name of the AE record in My Reviews to access the report.

Initial Review

3. Click Edit Reviewer Checklist to open the Reviewer Checklist.
4. If present, read the Staff Notes to Reviewer.
5. Review the details for each AE listed under the Reviewer Checklist.
6. Click the appropriate radio button in response to Condition Met.
7. If applicable, enter any additional identified issues for the study team in the Additional Issues field.
8. Optional: enter any personal notes (e.g., presentation notes) about the review in the Notepad field.
9. If applicable, attach any Supporting Review Documents by clicking Add. See Adding Supporting Documents procedure for details.
10. Click the appropriate radio button for Review Recommendation.
11. Click Continue >> to open the Submit Review page.

For a more detailed description of the Reviewer Checklist, see the Reviewer Checklist Field Descriptions.

12. If applicable, click the Check here if core committee staff can review ALL identified issues checkbox.
13. Click the appropriate radio button to answer the question Are you ready to submit your review?
14. Click Finish to exit the Submit Review page and save your work.

Note: You may edit and resubmit the review at any time until the determination for the submission is processed and the study team is notified. You can find the review under the In Progress tab on your Committee Member workspace.
Submitted - Home

A. Submitted shows that the review was submitted.

B. Activities displays all of the available activities for the review.
   - Edit Reviewer Checklist: Changes can be made to the reviewer checklist by clicking Edit Reviewer Checklist. Follow the same procedures as described above to resubmit the updated checklist.
   - Printer Friendly Version opens a review summary in a new window for printing.
   - Print Version of Submission opens the AE/ORIO submission in a new window for printing.
   - Change Log for Submission shows a history of changes that have been made to the submission.
   - Post Anonymous Correspondence: Notes can be created and then posted anonymously to the submission workspace. The notes are viewable by anyone with access to the submission, including study staff, office staff, reviewers and committee members.
   - Post Correspondence: Posts notes that include the editors’ name and are viewable by anyone with access to the submission. This includes study staff, office staff, reviewers and committee members.
   - For Reviewers and IRB Office: Allows for the posting of notes that will only be reviewable by the IRB staff and other committee members.

C. My Home returns to the inbox.
Adding Supporting Documents

1. Click **Add** under **Supporting review documents** (not shown).

2. Enter a **Title** for the document you are uploading or leave it blank.

   **Note:** Entering a title is optional. If you do not enter a title, the filename becomes the title of the document.

3. Use the **Browse** button to locate the document on your computer.

4. Select the file to upload from your computer and click **Open** (not shown).

5. Click **OK**.
Reviewer Checklist Field Descriptions

A. **Print Version of the Submission** opens up a single sheet copy of the submission.

B. **All Issues** displays all issues related to this study.

C. **Reviewer Checklist** displays the sections, reviewer checklist item, condition met, study team publication, and comments for each section of the application. It is also used to assign additional reviewers.

D. **Section** identifies the section of the submission that needs to be reviewed.

**Note:** You can also click on the section number to go directly to that section of the submission.

E. **Reviewer Checklist Item** displays the question and sub-set question needed for review.

F. Click the appropriate radio button for the Reviewer Checklist item in the **Condition Met** box.

G. **Comments** can be added for reference at a later date.

**Note:** When a condition is not met, a comment is required and will be converted to an identified issue upon submission.

H. The **Additional Issues** field can be used to identify additional issues for the study team.

I. The **Notepad** field can be used to report information not communicated to the office staff or study team.

J. **Supporting review documents** can be included by clicking on **Add**, if applicable. See Adding Supporting Documents procedure below for details.

K. Click the appropriate radio button for **Review Recommendation**.

L. Click **Continue** after reviewing the submission and completing the checklist.